1. RECALL INFORMATION

a. RECALL NUMBER

b. RECALLING ESTABLISHMENT

c. RECALLED CODE(S)

d. PRODUCT

2. PROGRAM DATA (CHECK BOX IF PREVIOUSLY SUBMITTED) ☐
(DO NOT COMPLETE IF REPORTED UNDER FDA 2123)

a. ACCOMP DISTRICT CODE	b. HOME DISTRICT CODE	c. OPERATION CODE	d. OPERATION DATE (MM/DD/YY)
		17	

e. CENTRAL FILE NUMBER OF RECALLING ESTABLISHMENT

f. PAC CODE

g. EMPLOYEE			h. TYPE	# OF CHECKS	HOURS
HOME DIST.	POS. CLASS	NUMBER	VISITS		
			PHONE		

3. AUDIT ACCOUNTS

a. DIRECT

PHONE NO.

b. SUB-ACCOUNT (SECONDARY)

PHONE NO.

c. SUB-ACCOUNT (TERTIARY)

PHONE NO.

4. CONSIGNEE DATA Contacted by: ☐ Phone ☐ Visit ☐ Other

a. NAME OF PERSON CONTACTED, TITLE & DATE

b. TYPE CONSIGNEE

☐ Wholesaler ☐ Physician
☐ Retailer ☐ Hospital ☐ Other
☐ Processor ☐ Pharmacy
☐ Consumer ☐ Restaurant

c. DOES (DID) THE CONSIGNEE HANDLE RECALLED PRODUCT?

☐ YES ☐ NO

5. NOTIFICATION DATA

a. FORMAL RECALL NOTICE RECEIVED?
(If "No" skip to item 6c.)

☐ YES ☐ NO ☐ CANNOT BE DETERMINED

b. RECALL NOTIFICATION RECEIVED FROM:

☐ Recalling Firm
☐ Direct Account
☐ Sub-Account
☐ Other *(Specify)*

c. DATE NOTIFIED

d. TYPE OF NOTICE RECEIVED (e.g. letter, phone)

6. ACTION AND STATUS DATA

a. DID CONSIGNEE FOLLOW THE RECALL INSTRUCTIONS? *(If "No", discuss in item 10 action taken upon FDA contact)*

☐ YES ☐ NO

b. AMOUNT OF RECALLED PRODUCT ON HAND AT TIME OF NOTIFICATION

c. CURRENT STATUS OF RECALLED ITEMS

☐ Returned ☐ Destroyed
☐ Corrected ☐ None on Hand
☐ Was Still Held for Sale/Use *
☐ Held For Return/Correction *
* = Ensure Proper Quarantine/Action

d. DATE AND METHOD OF DISPOSITION

7. SUB-RECALL NEEDED?
Did Consignee Distribute to any other Accounts?
(If "Yes" give Details in "Remarks" or Memo)

☐ YES ☐ NO

8. AMOUNT OF RECALLED PRODUCT NOW ON HAND

9. INJURIES/COMPLAINTS

IS CONSIGNEE AWARE OF ANY INJURIES, ILLNESS, OR COMPLAINTS?

☐ INJURY ☐ COMPLAINT
☐ ILLNESS ☐ NONE

If answer is other than "None', report details in a separate memo to monitoring district and copy to E.O.B. (HFC-162)

10. REMARKS *(Include action taken if product was still available for sale or use)*

SIGNATURE OF CSO/CSI

DISTRICT

DATE OF CHECK

TO:

DATE

SIGNATURE OF SCSO OR R&E COORDINATOR

ENDORSEMENT

FORM FDA 3177